

# Notice of Allowability

Application No.

09/242,343

Examiner

Zachariah Lucas

Applicant(s)

VOLLENBROICH ET AL.

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## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed February 10, 2004.
  2. ☒ The allowed claim(s) is/are 1-3,5-11,13-15 and 18.
  3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
  4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 4-28-2004.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-3, 5-11, 13-15, and 18 are pending and under consideration in the present application. In the prior action, mailed on May 19, 2003, claims 1-11, 13-15, and 18 were under consideration and rejected. In the Responses filed on November 19, 2003, and on February 10, 2004, the Applicant cancelled claim 4, and amended claims 1-3, 5-8, and 18.
2. For the reasons indicated below, claims 1-3, 5-11, 13-15, and 18 are allowed.

### **EXAMINER'S AMENDMENT**

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with MaryAnne Armstrong on April 28, 2004.

The application has been amended as follows:

Claim 1 has been amended by inserting the phrase - - up to 2 hours- - after the phrase "and for a time" on line 9 of the claim.

Claim 3 has been amended by deleting lines 2-4 of the claim, and inserting the following: - - characterized in that the cyclic lipopeptide is a naturally occurring lipopeptide, or

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is a chemically synthesized lipopeptide, or is a lipopeptide produced or modified by genetic engineering. - -

Claim 9 has been amended by deleting the term “lipid-developed” in line 2 of the claim, and inserting the phrase - - lipid-enveloped- - in its place.

Claim 11 has been amended by deleting the term “Lipoheptapeptides” in line 1 of the claim, and inserting the phrase “Isolated lipoheptapeptides” in its place.

Claim 18 has been amended by inserting the term - - wherein- - after the comma in line 1 of the claim.

The amendments of claims 3, 11, and 18 were made to correct minor errors in the claims.

The amendments of claims 1 and 3 were made for the reasons indicated in the Interview

Summary of April 28, 2004, and in the Reasons for Allowance provided below.

### ***Claim Objections***

4. **(Prior Objections- Withdrawn)** Claims 2 and 4 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the amendment of claim 2 such that it is now in independent form, and the cancellation of claim 4, the objections are withdrawn.

5. **(Prior Objection- Withdrawn)** Claim 3 was objected to because of the following informalities: it is suggested that the applicant clarify that “a chemically synthesized lipopeptide” is a separate choice from “a lipopeptide produced or modified by genetic engineering” by

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inserting a comma between the phrases “synthesized lipopeptide” and “or a lipopeptide produced...” In view of the amendments made by the Applicant, and those made in the Examiner’s Amendment above, the objection is withdrawn.

6. **(Prior Objection- Withdrawn)** Claim 18 was objected to because of the following informalities: in line 2, the claim refers to “biotechnologically produced product product.” Appropriate correction is required. It is suggested that the second “product” be deleted. In view of the amendments to claim 1 and claim 18, the objection is withdrawn.

***Claim Rejections - 35 USC § 112***

7. **(Prior Rejections- Withdrawn)** Claims 1-11, and 13-15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims were rejected because 1) it was unclear what was meant by the phrase “a purified product isolated from blood or a biotechnologically produced product substantially free of lipid enveloped viruses,” and 2) the claims read on methods of rendering products substantially free of lipid-enveloped viruses “by a factor of approximately  $>10^4$ .” The rejections are withdrawn in view of the amendment of the pending claims.

8. **(Prior Rejection- Withdrawn)** Claims 4-8, and 14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the cancellation of claim 4, and the amendment of the remaining claims such that they depend from claim 1, the rejection is withdrawn.

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9. **(Prior Rejection- Withdrawn)** Claims 1-10, 13-15, 18, and 19 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro inactivation of lipid-enveloped viruses, does not reasonably provide enablement for in vivo inactivation. In view of the amendment of the claims to read on methods of inactivating virus in an isolated protein composition, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

10. **(Prior Rejections-Withdrawn)** Claims 1, 3-7, 9, 10, 14, 15, 18, and 19 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Itokawa et al., Chem Pharm Bull 42(3): 604-607. Claims 2 and 13 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Itokawa or Naruse, in further view of Horowitz et al., Transfusion 25(6): 516-522. Also, Claims 8 and 11 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Itokawa, Naruse, and Vater et al., Proc 4<sup>th</sup> European Congress on Biotechnology 1987, Vol. 3, pages 266-269. The rejections are withdrawn in view of the amendments to the claims, and the Applicant's arguments pursuant thereto.

***Allowable Subject Matter***

11. The following is an examiner's statement of reasons for allowance:

While the Applicant's arguments were persuasive in part, the teachings of Itokawa in light of Weislow appear to demonstrate anticipation of claim 1 as drafted in the Response. This is because Itokawa states that the anti-HIV activity of the composition was tested using the

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method of Weislow, which comprises the contacting of a virus with the compound for period of 7 days. However, in the interview of April 28, 2004, the Examiner indicated that the claim would be allowable if the claim was amended such that the contacting step was limited to a time - - up to 2 hours- - as the teachings of Itokawa and Weislow do not teach such a limitation and provide no suggestion of such a limitation (for the reasons argued by the Applicant- i.e. the teachings of moderate activity after 7 days). Thus, while the reference would appear to anticipate claims comprising the contacting virus with the compound, they do not anticipate or render obvious claims consisting of contacting virus with the compound for up to 2 hours.

The Examiner also requested the Amendment of claim 11 such that the claim reads on isolated lipopeptides. This request was to avoid a possible rejection of the claim under 35 U.S.C. 101 for reading on non-statutory subject matter: a product of nature. In view of the amendment of the claim, it appears to be in allowable condition.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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